K113236
P1/5

510(k) Summary

FEB 12 2013

1. Submitter Information

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Application Correspondent Information:

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2. Subject Device Information

Type of 510(k) submission:	Traditional
Common Name:	Negative Pressure Wound Therapy Device
Trade Name:	Foryou NPWT NP32 Device
Classification Name:	Negative Pressure Wound Therapy Powered Suction Pump
Review Panel:	General & Plastic Surgery
Product Code:	OMP
Regulation Number:	21 CFR 878.4780
Regulation Class:	2

3. Predicate Device Information

Sponsor:	Smith & Nephew, Inc.	KCI USA. Inc.

Device Name:	RENASYS* EZ Plus Negative Pressure Wound Therapy	ActiV.A.C. Therapy Unit
510(k) Number:	K082426	K063692
Product Code:	OMP	OMP
Regulation Number:	21 CFR 878.4780	21 CFR 878.4780
Regulation Class:	2	2

4. Device Description

Foryou NPWT NP32 Device is an AC-powered, portable suction pump with a back-up battery. The pump is used in combination with wound dressing kits, a bacteria filter, suction tubing, drainage tubing, and a disposable canister. Foryou NPWT NP32 Device is designed for hospital use only with specified wound dressing kits to deliver a recommended therapeutic range of -55mmHg — -155mmHg of continuous or intermittent negative pressure wound therapy to the wound, which may promote wound healing through the removal of excess exudates, infectious material, and tissue debris by:

- preparing the wound bed for closure
- reducing edema
- promoting granulation tissue formation and perfusion
- removing exudate and infectious material

The wound dressing kits, bacteria filter, suction tubing, drainage tubing, and disposable canister are not included in the Foryou NPWT device package.

5. Intended Use

Foryou NPWT NP32 Device is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing through the removal of excess exudates, infectious material, and tissue debris.

6. Non-Clinical Testing

Non-clinical testing was performed to assess the safety and effectiveness of the Foryou NPWT NP32 Device. The non-clinical tests included bench testing using a mock wound model, electrical safety testing, EMC compatibility testing, biocompatibility testing, software unit testing and software integration testing. The electrical safety and EMC compatibility tests were conducted in accordance with IEC 60601-1 and IEC 60601-1-2, respectively. All tests that were created for the Foryou NPWT NP32 had passing results with acceptance criteria successfully met, which demonstrates the safety & effectiveness of the device.

The following FDA Guidance Documents were used as part of this submission package.

- Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT); November 10, 2010
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; May 2005

7. Comparison to Predicate Device

The Foryou NPWT NP32 Device has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Foryou NPWT NP32 Device and its predicate devices raise no new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Devices		Verdict
Product Name	Foryou NPWT NP32 Device	RENASYS EZ	ActiV.A.C. Therapy Unit	--
K Number	Applying	K082426	K063692	--
Product Code	OMP	OMP	OMP	SE
Regulation Number	21 CFR 878.4780	21 CFR 878.4780	21 CFR 878.4780	SE
ELECTRICAL REQUIREMENT				
Device Rating	Power Input: 100—240Vac, 47—63Hz, 1.62—0.72A	Power Input: 100—240Vac, 50/60Hz, 90VA	Power Input:100-240Vac, 47—63 Hz, .72A @ 115Vac	Note 1
PERFORMANCE SPECIFICATION				
Maximum Vacuum	155 mmHg	200mmHg	200mmHg	SE Note 2
Battery Life	About 20 hours (-155mmHg continuous operation)	About 40 hours	14 hours	SE Note 2
Earth Protection	Class II	Class II	Class II	SE
Patient Protection	Type B	Type BF	Type B	Note 2
Ingress Protection	IPX1	IPX2	IPX0	Note 3
Operating Mode	Continuous or Intermittent Mode	Continuous or Intermittent Mode	Continuous or Intermittent Mode	SE
DIMENSIONS/WEIGHT				
Dimensions	270mm x 228mm x 205mm	361mm x 240mm x 170mm	193 x 152 x 64 mm	Note 2
Weight	2.4kg	3.3kg	1.08Kg	
OPERATING & STORAGE CONDITIONS				

Elements of Comparison	Subject Device	Predicate Devices		Verdict
Storage Environment	Temperature: -10—50℃ Humidity: 5—85% RH Atmospheric Pressure: 700—1060hPa	Temperature: -10—55℃ Humidity: 30—70% RH Atmospheric Pressure: 700—1060hPa	Temperature: -20—60℃ Humidity: 0—95% RH Atmospheric Pressure: 700—1060hPa	Note 2
Working Environment	Temperature: 0—40℃ Humidity: 30—75% RH Atmospheric Pressure: 700—1060hPa	Temperature: 5—35℃ Humidity: 30—70% RH Atmospheric Pressure: 700—1060hPa	Temperature: 5—40℃ Humidity: 0—95% RH Atmospheric Pressure: 700—1060hPa	Note 2
Evaluation				
Electrical, Mechanical and Thermal Evaluation	IEC 60601-1:1988+A1:1991+A2:1995 IEC 60601-1-2:2007	IEC 60601-1:1988+A1:1991+A2:1995 IEC 60601-1-2:2007	IEC 60601-1:1988+A1:1991+A2:1995 IEC 60601-1-2:2007	SE
Biocompatibility Evaluation	The recommended accessories are FDA cleared, which are evaluated by the biocompatibility standard ISO 10993 -5, -10.	The biocompatibility of the accessories is evaluated as per the requirements of the ISO 10993 -5, -10 standards.	The biocompatibility of the accessories is evaluated as per the requirements of the ISO 10993 -5, -10 standards.	SE
Recommended Accessories				
Wound Dressing Kit	Smith & Nephew NPWT Foam Dressing Kits	Smith & Nephew NPWT Foam Dressing Kits	--	SE
Canister Kit	Bemis Health Care, 800cc Suction Canister	Smith & Nephew 800cc Suction Canister	--	Note 4
Bacteria Filter	Porous Media, DDF47 Bacteria Filter	In-Line Bacteria Overflow Filter	--	

Note 1

Both the subject device and the predicate devices are in compliance with IEC 60601-1:1988+A1:1991+A2:1995. The differences in their ratings do not affect the safety and effectiveness.

Note 2

Although there are some differences in performance specifications, dimensions/weight, and operating & storage conditions between the subject device and the predicate devices, these differences do not affect

the safety and effectiveness. Both the subject device and the predicate devices are in compliance with IEC 60601-1:1988+A1:1991+A2:1995 and "Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT)".

Note 3

The ingress testing was evaluated through risk management and determined to be acceptable at IPX1.

Note 4

Foryou NPWT NP32 Device is defined as a NPWT pump only and the device package does not include the recommended accessories in the User Manual. The recommended accessories are similar to the predicate devices and were evaluated during performance testing.

8. Conclusion

The Foryou NPWT NP32 Device is as safe and effective as its predicate devices. The Foryou NPWT Device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Foryou NPWT NP32 Device and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Foryou NPWT NP32 Device is as safe and effective as its predicate devices. Thus, the Foryou NP32 NPWT Device is substantially equivalent.

9. Summary Prepared Date

9 January 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Foryou Medical Electronics Company, Limited
% Regulatory and Quality Solutions, LLC
Mr. Scott Wright
Principal Regulatory and Quality Advisor
3919 William Penn Highway, Suite 200
Murrysville, Pennsylvania 15668

February 12, 2013

Re: K113236
Trade/Device Name: Foryou NPWT NP32 Device
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 18, 2013
Received: January 17, 2013

Dear Mr. Wright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Peter D. Rumm -S
Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113236

Indications for Use Statement

510(k) Number (if known): K113236

Device Name: Foryou NPWT NP32 Device

Indications for Use:

Foryou NPWT NP32 Device is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing through the removal of excess exudates, infectious material, and tissue debris.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang

(Division Sign-Off)
Division of Surgical Devices
510(k) Number __K113236_____